Calendar No. 105

105TH CONGRESS
1ST SESSION

S. 830

[Report No. 105–43]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

JULY 1, 1997

Reported under authority of the order of the Senate of June 27, 1997, with an amendment

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IN THE SENATE OF THE UNITED STATES

JUNE 5, 1997

Mr. JEFFORDS (for himself, Mr. DODD, Mr. COATS, Ms. MIKULSKI, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

JULY 1, 1997

Reported under authority of the order of the Senate of June 27, 1997, by Mr. JEFFORDS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Modernization and Accountability Act of 1997''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. REFERENCES.

Except as otherwise expressly provided, wherever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

TITLE I—IMPROVING PATIENT ACCESS

SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) by adding after subsection (a) the following:

"(b) MISSION.—

"(1) IN GENERAL.—The Food and Drug Administration shall protect the public health by ensuring that—

"(A) foods are safe, wholesome, and sanitary;

"(B) human and veterinary drugs are safe and effective;

"(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

"(D) cosmetics are safe; and

"(E) public health and safety are protected from electronic product radiation.

"(2) SPECIAL RULES.—The Food and Drug Administration shall promptly and efficiently review clinical research and take appropriate action on the

marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements.''.

SEC. 102. EXPEDITED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SUBCHAPTER D—UNAPPROVED THERAPIES AND DIAGNOSTICS

''SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

''(a) IN GENERAL.—Any person, acting through a medical practitioner licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to a person after compliance with the provisions of this section, an investigational drug (including a biological product) or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition, or any other disease or condition designated by the Secretary as appropriate for expanded access under this section if—

''(1) the licensed medical practitioner determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved;

''(2) the licensed medical practioner determines that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

''(3) the Secretary determines that an exemption for the investigational drug or investigational device is in effect under a regulation promulgated pursuant to section 505(i) or 520(g) and the sponsor of the drug or device and investigators comply with such regulation;

''(4) the Secretary determines that the manufacturer of the investigational drug or investigational device is actively pursuing marketing approval with due diligence; and

''(5) expanded access will not interfere with adequate enrollment of patients by the investigator in the ongoing clinical investigation authorized under section 505(i) or 520(g).

''(b) PROTOCOLS.—A manufacturer or distributor may submit to the Secretary 1 or more expanded access protocols covering expanded access use of a drug or device

described in subsection (a). The protocols shall be subject to the provisions of section 505(i) or 520(g) and may include any form of use of the drug or device outside a clinical investigation, prior to approval of the drug or device for marketing, including protocols for treatment use, emergency use, or uncontrolled trials, and single patient protocols.

''(e) NOTIFICATION OF AVAILABILITY.—The Secretary shall inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this section.''.

(d) TERMINATION.—FDA may at any time terminate expanded access under subsection (a) if the requirements under this section are no longer met.

SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding at the end the following flush sentences:

''The request shall be in the form of an application submitted to the Secretary. Not later than 60 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) in paragraph (4)(B), by inserting after ''(2)(A)'' the following: '', unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and after making a good faith effort, the physician does not receive a timely response from an institutional review committee on the physician's request for approval to use the device.

(3) by striking paragraph (5) and inserting the following:

''(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met. Nothing in this section shall be construed to prevent the Secretary from using any of the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520, any combination of such controls, or any of the special controls established under section 513(a)(1)(B), in connection with a device for which an exemption has been granted under paragraph (2).''.

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

SEC. 201. INTERAGENCY COLLABORATION.

Section 903(b) (21 U.S.C. 393(b)) is amended by adding at the end the following:

''(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the Secretary's duties with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.''.

SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.

It is the sense of the Committee that—

(1) the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, should move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food addi-

tives, and color additives, and the regulation of good manufacturing practices, reached between the European Union and the United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

SEC. 203. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 906. CONTRACTS FOR EXPERT REVIEW.

"(a) IN GENERAL.—

"(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Sec-

retary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

''(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1). Such improvement may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

''(b) REVIEW OF EXPERT'S EVALUATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final

decision regarding the matter within 60 days after receiving the recommendations.

''(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of the matter as set forth in this Act.

''(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, or the classification of an article as a device under section 513(f)(1).''.

SEC. 204. ACCREDITED-PARTY REVIEWS.

Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 523. ACCREDITED-PARTY PARTICIPATION.

''(a) ACCREDITATION.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit persons, including any entity or individual who is not an employee of United States Government, to review and make recommendations regarding submissions made to the Secretary under section 510(k) except that this paragraph does not apply to submissions for devices that are—

‘‘(A) life-supporting;

‘‘(B) life sustaining; or

‘‘(C) intended for implantation in the human body for a period of over 1 year.

‘‘(2) SPECIAL RULE.—The Secretary shall have the discretion to accredit persons, including any entity or individual who is not an employee of the United States Government, to review and make recommendations regarding devices described in subparagraphs (A) through (C) of paragraph (1) or devices subject to premarket approval under section 515.

‘‘(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that persons who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.

‘‘(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any person accredited under this section, after providing notice and an opportunity for an informal hearing, if such person

acts in a manner that is substantially not in compliance with the requirements established by the Secretary, including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

''(d) SELECTION AND COMPENSATION.—A person who intends to submit a premarket submission for a device to the Secretary under subsection (a) shall have the option to select an accredited person to review such submission. Upon the request of a person intending to make a premarket submission for a device, the Secretary shall identify for the person no less than 2 accredited persons from whom the selection may be made. Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person and shall be paid by the person who engages such services.

''(e) REVIEW BY SECRETARY.—The Secretary shall require an accredited person, upon recommending a classification of a device or approval or disapproval of an application for a device, to report to the Secretary the reasons of the accredited person for such recommendation of classification or approval or disapproval. For devices reviewed and initially classified under section 513(f)(1) and subject to a report under section 510(k), the Secretary shall have

not more than 30 days to review the submission. For applications submitted under section 515(c)(1), the Secretary shall have not more than 60 days to review the application. The Secretary may change the classification under section 513(f)(1), or the approval or disapproval of the application under section 515(d), that is recommended by the accredited person, and in such case shall notify in writing the person making the submission of the detailed reasons for the change.

''(f) DURATION.—The authority provided by this section terminates—

''(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review devices in each of at least 70 percent of generic types of devices required for review under subsection (a); or

''(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices required for review under subsection (a) that were the subject of final action by the Secretary in the fiscal year preceding the date on which the Secretary notifies the Congress were reviewed by the Secretary under subsection (c),

whichever occurs first.

''(g) REPORT.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited persons under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).

''(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited persons to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited persons (including review times, recommendations, and compensation), and data on the review of the Secretary (including review times, changes, and reasons for changes).''.

SEC. 205. DEVICE PERFORMANCE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

''RECOGNITION OF A STANDARD

''(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet premarket submission requirements or other requirements under this Act to which such standards are applicable.

''(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.

''(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under the Act.

''(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless, the Secretary finds—

''(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

''(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

''(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

''(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the Secretary's classification or approval of the device or a time equal to the expected design life of a device, whichever is longer.''.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(x) The falsification of a declaration of conformity under subsection (c)(3) of section 514 or the failure or refusal to provide data or information requested by the Secretary under such subsection.''.

(c) SECTION 501.—Section 501(c) (21 U.S.C. 351(c)) is amended—

(1) by striking ''(c)'' and inserting ''(c)(1)''; and

(2) by inserting at the end the following:

''(2) If it is, purports to be, or is represented as, a device that is declared to be in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.''.

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

''(C)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence within the meaning of sub-

paragraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person. Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary that such data are necessary to establish device effectiveness and that no other less burdensome means of evaluating device effectiveness are available which would have a reasonable likelihood of resulting in an approval.

''(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless—

''(I) such determination by the Secretary would be contrary to the public health; or

''(II) based on new information obtained by the Secretary prior to the approval of an application for an investigational device exemption under section

520(g), the Secretary finds that such determination is scientifically inappropriate.''.

SEC. 302. COLLABORATIVE REVIEW PROCESS.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (4)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A) The Secretary shall meet with an applicant not later than 100 days after the receipt of an application that has been filed as complete under subsection (c) to discuss the review status of the application. If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting, provide to the applicant a description of any deficiencies in the application identified by the Secretary and identify the information (other than information the Secretary needs to making a finding under paragraph (4)(C)) that is required to bring the application into a form that would require an approval. The Secretary and the applicant may, by mutual consent, es-

tablish a different schedule for a meeting required under this paragraph.

''(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).''.

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

SEC. 401. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking ''(a) The'' and inserting ''(a)(1) The''; and

(2) by adding at the end the following:

''(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate as a regulation in the Federal Register the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.''.

SEC. 402. PRODUCT CLASSIFICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''SUBCHAPTER D—REVIEW OF APPLICATIONS AND ENVIRONMENTAL IMPACT REVIEWS

"SEC. 741. CONTENT AND REVIEW OF AN APPLICATION OR SUBMISSION.

''(a) CLASSIFICATION OF A PRODUCT.—

''(1) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act, may submit a request to the Secretary respecting the classification of an article (including an article that is a combination product subject to section 503(g)) as a drug, biological product, or device, or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or the component that should regulate the article, as appropriate.

''(2) STATEMENT.—Not later than 60 days after the receipt of the request described in paragraph (1), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administra-

tion that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

''(3) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in paragraph (2), the recommendation made by the person under paragraph (1) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.''.

SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.

Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

''(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6

years after the application has been approved by the Secretary, for use by the Secretary in—

''(i) approving devices;

''(ii) determining whether a product development protocol has been completed, under section 515;

''(iii) establishing a performance standard or special control under section 514; and

''(iv) classifying or reclassifying devices under section 513 and subsection (l)(2).

''(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).''.

SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.

(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:

''In making the determination whether to approve or deny an application, the Secretary shall rely on the conditions of use proposed in the labeling of a device as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness. If, based on a fair

evaluation of all material facts, the proposed labeling is neither false nor misleading in any particular, the Secretary, in making the determination, shall not consider conditions of use not included in the proposed labeling.''.

(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

''(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

''(D) Any determinations of substantial equivalence by the Secretary shall be based upon the intended uses proposed in labeling submitted in a report under section 510(k).''.

SEC. 405. DEFINITION OF A DAY FOR PURPOSES OF PRODUCT REVIEW.

Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ii) In any provision relating to a review of any application or submission (including a petition, notification,

and any other similar form of request), made under this Act with respect to an article that is a new drug, device, biological product, new animal drug, an animal feed bearing or containing a new animal drug, color additive, or food additive, that is submitted to the Secretary to obtain marketing approval, to obtain classification of a device under section 513(f)(1), or to establish or clarify the regulatory status of the article, the term 'day' means a calendar day in which the Secretary has responsibility to review such an application or submission (excluding any calendar day between the date of receipt, by the person submitting the application or submission, of a written communication from the Secretary setting forth the action of the Secretary on the application or submission and the date of receipt by the Secretary of the written response of the person to the action).''.

SEC. 406. CERTAINTY OF REVIEW TIMEFRAMES.

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

''The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the notification.''.

(b) CERTAINTY OF 180-DAY REVIEW TIME FRAME.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

''(3) The time for the review of an application by the Secretary under this subsection shall take not more than 180 days and such time may not be extended if the application is amended.''.

SEC. 407. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

''(m)(1) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f).

''(2) Nothing in this provision shall be construed to prevent the Secretary from using any of the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520, or any combination of such controls, or any of the special controls established under section 513(a)(1)(B) to regulate a marketed device.''.

SEC. 408. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.

Not later than 270 days after the date of enactment of this section, the Secretary shall promulgate a final regulation specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(f)(1)) .

SEC. 409. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking ''clinical investigations'' and inserting ''one or more clinical investigations''.

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''If the Secretary determines that only one investigation is required, then the Secretary may require appropriate supporting scientific evidence obtained prior to or after such investigation. The Secretary shall establish a mechanism to ensure the fair and consistent application of this provision to new drugs''.

SEC. 410. PROHIBITED ACTS.

Section 301(*l*) (21 U.S.C. 331(*l*) is repealed.

TITLE V—IMPROVING ACCOUNTABILITY

SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

"(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, and representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

"(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives for and mechanisms to be used

by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

"(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

"(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

"(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

"(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

"(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods speci-

fied in this Act for the review of all applications and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

"(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

"(5) ANNUAL REPORT.—

"(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

"(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

"(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

‘‘(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

‘‘(iv) identifies any regulatory policy that has a significant impact on compliance with any objective of the plan or any statutory obligation; and

‘‘(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

‘‘(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

‘‘(i) the submission of any investigational application;

‘‘(ii) the application of any clinical hold;

''(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

''(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

''(v) the occurrence of any unapprovable action;

''(vi) the occurrence of any approvable action; and

''(vii) the approval or clearance of any application or submission described in clause (iii).''.

TITLE VI—INCREASING RESOURCES BY SETTING PRIORITIES

SEC. 601. MINOR MODIFICATIONS.

(a) PROCEDURES AND CONDITIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal

Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from certain requirements under this Act.

''(B) The regulation shall permit developmental changes in devices (including manufacturing changes) in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to such application, if the sponsor of the investigation determines, prior to making any changes, that the changes—

''(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

''(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.''.

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

''(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section

520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

"(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under section 515(c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

"(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device subject to the pending application.".

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

"(6)(A) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the

holder of an approved application submits a written notice to the Secretary that describes the change and informs the Secretary that the change has been made under the requirements of section 520(f).

''(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

''(I) nonclinical data demonstrate that a design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification to provide a reasonable assurance of safety and effectiveness.''.

SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

''SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

''Notwithstanding any other provision of law, no action by the Secretary pursuant to this Act shall be subject to an environmental assessment, an environmental impact statement, or other environmental consideration unless the Secretary demonstrates, in writing—

''(1) that there is a reasonable probability that the environmental impact of the action is sufficiently substantial and within the factors that the Secretary is authorized to consider under this Act; and

''(2) that consideration of the environmental impact will directly affect the decision on the action.''.

SEC. 603. EXEMPTION OF CERTAIN CLASS DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.

Section 510 (21 U.S.C. 360) is amended inserting after subsection (k) the following:

''(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k)

as of the date of the publication of the list in the Federal Register.

''(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, any person may petition the Secretary to exempt a type of class II device from the notification requirement of subsection (k). The Secretary shall publish notice of the petition in the Federal Register and provide a 30-day period for public comment. The Secretary shall respond to the petition within 120 days after the receipt of the petition and determine whether or not to grant the petition in whole or in part.''.

SEC. 604. REVIEW OF CLASS I AND CLASS II DEVICES.

(a) EXEMPTION FROM PREMARKET NOTIFICATION.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 unless such device is intended for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))''.

SEC. 605. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and which is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device into class I or II under the criteria set forth in subsection (a)(1). The person may, in the request, recommend to the Secretary the classification for the device. The request shall describe the device and provide detailed information and reasons for the recommended classification.

''(B)(i) Not later than 60 days after the date of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of section 513(a)(1), the Secretary shall by written order classify the device. Such classification shall

be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph into class I or II shall be a predicate device for determining substantial equivalence under paragraph (1).

''(ii) A device that remains in class III under this subparagraph shall be deemed adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

''(C) Following the issuance of an order classifying a device under this paragraph, the Secretary shall, within 30 days after the date of the issuance of the order, publish a notice in the Federal Register announcing such classification.''.

SEC. 606. SECRETARY'S DISCRETION TO TRACK DEVICES.

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

''Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.''.

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act,

the Secretary shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)). Each device not identified by the Secretary under this subsection shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act.

SEC. 607. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—Section 522 (21 U.S.C. 360*l*) is amended by striking ''SEC. 522.'' and all that follows through ''(2) DISCRETIONARY SURVEILLANCE.—The'' and inserting the following:

''SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The''.

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360*l*(b)) is amended to read as follows:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall, not later than 30 days after receiving notice from the Secretary that the manufacturer is required under this section to conduct the surveillance, submit for the approval of the Secretary, a plan for the required surveillance.

''(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed to be used to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

''(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.''.

(c) DURATION OF SURVEILLANCE.—Section 522 (21 U.S.C. 360*l*), as amended by subsection (b), is further amended by adding at the end the following:

''(e) DURATION OF SURVEILLANCE.—

''(1) IN GENERAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a) shall be required to conduct such surveillance for not longer than 24 months.

''(2) EXTENSION OF THE PERIOD OF SURVEILLANCE.—If the Secretary determines that additional

surveillance is needed to identify the incidence of adverse events documented during the initial period of surveillance that were not foreseen at the time of approval or classification of the device, the Secretary may extend the period of surveillance for such time as may be necessary after providing the person required to conduct such surveillance an opportunity for an informal hearing to determine whether or not additional surveillance is appropriate and to determine the appropriate period, if any, for such surveillance.''.

SEC. 608. REPORTING.

Section 519 (21 U.S.C. 360i) is amended—

(1) by striking '', importer, or distributor'' each place it appears and inserting ''or importer'';

(2) in subsection (a)—

(A) in paragraph (7), by striking the semicolon at the end and inserting ''; and'';

(B) in paragraph (8), by striking ''; and'' and inserting a period; and

(C) by striking paragraph (9); and

(3) by striking subsection (d).

SEC. 609. PILOT AND SMALL-SCALE MANUFACTURE.

Section 505(e) (21 U.S.C. 355(e)) is amended by adding at the end the following:

''(4) An application shall be approved based on information obtained from products manufactured in a pilot or other small facility so long as the commercial manufacturing process is validated prior to product distribution pursuant to a protocol submitted with the application, unless the Secretary specifies in writing the reasons why information from a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

SEC. 610. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall establish proposed regulations governing the approval of radiopharmaceutical articles designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the safety and effectiveness of a radiopharmaceutical shall be evaluated taking into account the appropriate use of radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical, and the estimated absorbed ra-

diation dose of the radiopharmaceutical. Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate the final regulations governing the approval of the radiopharmaceutical.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic purposes, the indications for which such radiopharmaceutical is approved for marketing may refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to or present in 1 or more disease states, or may refer to a diagnostic procedure used in the diagnosis of 1 or more diseases or conditions.

(b) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in vivo in the diagnosis, cure, mitigation, treatment, or prevention of a disease or a manifestation of disease in man; and

(B) that exerts its primary effect through its pharmacokinetics and the spontaneous disintegration of unstable nuclei with the emission of ionizing radiation; or

(2) a reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 611. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

REGULATION OF BIOLOGICAL PRODUCTS

"SEC. 351. (a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

"(A) a biologics license is in effect for the biological product; and

"(B) each package of the biological product is plainly marked with the proper name of the biological product contained in the package, the name, address, and applicable license number of the manufacturer of the biological product, and the expiration date of the biological product.

"(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

"(B) A biologics license application shall be approved based upon a demonstration that—

''(i) the biological product that is the subject of the application is safe, pure, and potent; and

''(ii) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

''(3) A demonstration under paragraph (2)(B)(i) may be made on the basis of 1 or more clinical trials, or other requirements established by the Secretary under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

''(4) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).''.

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(B) in paragraph (2),

(i) by striking ''(2)(A) Upon'' and inserting ''(d)(1) Upon''; and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2), (as so redesignated by subparagraph (B)(ii)), by striking ''subparagraph (A)'' and inserting ''paragraph (1)''.

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container so as to falsify the label or mark.''.

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows and inserting ''biological product.''.

(d) DEFINITION; APPLICATION.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

''(i) For purposes of this section, the term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or conditions of human beings.''.

(c) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A), by striking ''section 351(a)'' and inserting ''section 351(i)''; and

(2) in subparagraph (B)(iii), by striking ''product or establishment license under subsection (a) or (d)'' and inserting ''biologics license application under subsection (a)''.

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have biological license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

SEC. 612. SUPPLEMENTAL NEW DRUG APPLICATIONS.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following:

''(7) The Secretary may approve a supplement to an approved application for an additional use for the drug on the basis of literature reports, reliable clinical experience, or persuasive scientific evidence, the totality of which is sufficient to demonstrate the effectiveness of the drug for the use involved.''.

SEC. 613. HEALTH CARE ECONOMIC INFORMATION.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(u) In the case of a health care economic statement that is included in labeling or advertising provided to a formulary committee, managed care organization, or similar entity with responsibility for drug selection decisions (other than the label or approved physician package insert relating to an indication approved under section 505 or 351 of the Public Health Service Act) if the health care economic statement is not competent and reliable. Any such statement shall be subject solely to this paragraph. In this paragraph, the term 'health care economic statement' means any statement that identifies, measures, or compares the costs (direct, indirect, and intangible) and health care consequences of a drug to another drug or to another health care intervention for the same indication, or to no intervention, where the primary endpoint is an economic outcome.''.

SEC. 614. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

‘‘SUBCHAPTER E—FAST TRACK DRUGS

‘‘SEC. 561. FAST TRACK DRUGS.

‘‘(a) DESIGNATION OF DRUG AS A FAST TRACK DRUG.—

‘‘(1) IN GENERAL.—The Secretary shall facilitate development, and expedite approval, of new drugs and biological products that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. For purposes of this Act, such products shall be known as ‘fast track drugs’.

‘‘(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a fast track drug. A request for designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i).

‘‘(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request is being, or will be, investigated for treatment of a condition described in paragraph (1). If the Secretary finds that the drug is intended for such treatment, the Secretary shall

~~designate the drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.~~

~~"(b) APPROVAL OF APPLICATION FOR A FAST TRACK DRUG.—~~

~~"(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track drug under section 505(b) or section 351 of the Public Health Service Act upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.~~

~~"(2) LIMITATION.—Approval under this subsection may be subject to the requirement that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug.~~

~~"(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK DRUG.—~~

~~"(1) IN GENERAL.—The Secretary shall, after completion of the pivotal clinical trial for a fast track drug under investigation, accept for filing and commence review of an incomplete application for the drug's approval if the application includes a schedule for submission of information necessary to~~

make the application complete and any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications agreed to by the Secretary under section 736 shall not apply to applications submitted under paragraph (1) until a completed application is submitted.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and widely disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies and other appropriate persons a comprehensive description of the provisions applicable to fast track drugs established under this section; and

''(2) establish an ongoing program to encourage the development and use of surrogate endpoints that are reasonably likely to predict clinical benefit for all serious and life-threatening conditions for which there exist significant unmet medical needs.''.

(b) REGULATIONS.—Within 90 days after the date of enactment of this Act, the Secretary shall issue guidelines for fast track drugs that implement the requirements of section 561 of the Federal Food, Drug, and Cosmetic Act.

SEC. 615. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:

''SUBCHAPTER E—MANUFACTURING CHANGES

''SEC. 751. MANUFACTURING CHANGES.

''(a) IN GENERAL.—A change in the manufacture of a new drug, including a biological product, may be made in accordance with this section.

''(b) CHANGES.—

''(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, or license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

''(2) REPORTS.—The applicant shall report a change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:

"(A)(i) Major manufacturing changes, which are of a type determined by the Secretary to have a substantial potential to adversely affect the identity, strength, quality, purity, and potency as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.

"(ii) In this subparagraph, the term 'major manufacturing changes' means—

"(I) changes in the qualitative or quantitative formulation or the specifications in the approved marketing application (unless exempted by the Secretary);

"(II) changes which the Secretary determines by regulation or guidance require completion of an appropriate human study demonstrating equivalence to the drug manufactured before such changes; and

"(III) other changes which the Secretary determines by regulation or guidance have a substantial potential to ad-

versely affect the safety or effectiveness of the drug.

''(B)(i) As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—

''(I) be made at any time and reported annually to the Secretary, with supporting data; or

''(II) be reported to the Secretary in a supplemental application.

''(ii) In the case of changes made in accordance with clause (i)(II);

''(I) the applicant may distribute the drug 30 days after the supplemental application is received by the Secretary unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required; and

''(II) the Secretary shall, after the notification to an applicant under subclause (I), approve or disapprove each such supplemental application.

''(ii) The Secretary may determine types of manufacturing changes after which distribution

of a drug may commence at the time of submission of such supplemental application.''.

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect for—

(1) a period of 24 months after the date of the enactment of this Act; or

(2) until the effective date of regulations promulgated by the Secretary implementing section 751 of the Federal Food, Drug, and Cosmetic Act,

whichever is sooner.

SEC. 616. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary, through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports in lieu of full reports may be submitted with a new drug application for certain types of studies. Such guidance will describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 617. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1), by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

"(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

"(B) a notification submitted under subsection (h) which is effective."; and

(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance , is in effect, and has not been revoked pursuant to subsection (j), a food

shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).''.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

''NOTIFICATION RELATING TO A FOOD CONTACT SUBSTANCE

''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information re-

quired to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

''(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

''(C) For purposes of this paragraph, 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

''(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is nec-

essary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

''(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for matters in the notification that is a trade secret or confidential commercial information.

''(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be based on the resources required to process the notification including reasonable administrative costs for such processing.

''(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of this subsection, promulgate regulations establishing the fee required by subparagraph (A).

''(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of paragraph (3) until the appropriate fee is paid.

''(D) Fees collected pursuant to this subsection—

''(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

''(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

''(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of the enactment of this Act.

SEC. 618. HEALTH CLAIMS OF FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause shall be authorized and may be made if—

''(i) an authoritative scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control

and Prevention), the National Academy of Sciences, or subdivisions of the scientific body or the National Academy of Sciences, has published statements, conclusions, or recommendations in effect recognizing that the relationship between the nutrient and disease or health-related condition to which the claim refers is supported by pertinent scientific evidence; and

''(ii) the manufacturer or distributor of the food for which such claim is made has submitted to the Secretary at least 90 days before the first introduction of such food into interstate commerce a notice of claim, including a concise description of the basis upon which such manufacturer or distributor relied for determining that the requirements of clause (i) have been satisfied.''.

SEC. 619. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1) the Secretary determines that information relating to the use of a drug in the pediatric popu-

lation may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a time frame for completing such studies), and such studies are completed within any such time frame and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such time frame and the reports thereof are accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and

for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions), or

"(ii) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV), and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE

BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a time frame for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such time frame and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such time frame and the reports thereof accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and

(j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II) and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions), or

"(ii) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV), and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

"(A) the sponsor of an application for an investigational new drug under section 505(i),

"(B) the sponsor of an application for a drug under section 505(b)(1), or

"(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

"(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder

and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

"(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly

respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

''(c) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j), respectively, until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any

determination that the requirements of subsection (d) have been met and that submissions and approvals under section 505(b)(2) or (j) for a drug will be subject to the provisions of this section.

''(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.

''(h) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or subsection (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).''

''(i) SUNSET.—No period of market exclusivity shall be granted under this section based on studies commenced after January 1, 2004. The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

''(2) the adequacy of the incentive provided under this section;

''(3) the economic impact of the program; and

''(4) any suggestions for modification that the Secretary deems appropriate.''.

TITLE VII—FEES RELATING TO DRUGS

SEC. 701. SHORT TITLE.

This title may be cited as the ''Prescription Drug Users Fee Reauthorization Act of 1997''.

SEC. 702. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy the benefits provided by the drugs to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992, has been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of _____; and _____; from the Secretary of Health and Human Services to the Chairman of the Committee on Commerce of the House of Representatives and the Chairman of Committee on Labor and Human Resources Committee of the Senate, as set forth at ____ Cong. Rec. _____ (daily ed. _____; 1997).

SEC. 703. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in paragraph (1)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include an application for a biological product that is licensed for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug or biological product that is not distributed commercially. Such term does include an application for a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(2) in paragraph (3)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a biological product that is not distributed commercially and is the subject of a supplement or application submitted by a State

or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(3) in paragraph (4), by striking ''without'' and inserting ''without substantial'';

(4) in paragraph (7)(A), by striking ''employees under contract'' and all that follows through ''Administration,'' and inserting ''contractors of the Food and Drug Administration,'';

(5) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking ''August of'' and inserting ''April of''; and

(ii) by striking ''August 1992'' and inserting ''April 1992''; and

(B) by striking subparagraph (B) and inserting the following:

''(B) the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title

for Federal employees stationed in the District of Columbia.''; and

(6) by adding at the end the following:

''(9) The term 'affiliate' means, directly or indirectly,—

''(A) 1 business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control both of the business entities described in subparagraph (A).''.

SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.'';

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking ''NOT ACCEPTED'' and inserting ''REFUSED'';

(ii) by striking ''50 percent'' and inserting ''75 percent'';

(iii) by striking ''subparagraph (B)(i)'' and inserting ''subparagraph (B); and

(iv) by striking ''not accepted'' and inserting ''refused''; and

(C) by adding at the end the following:

''(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526, or a supplement proposing to include a new indication for a rare disease or condition pursuant to section 526, shall not be assessed a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions.

''(F) EXCEPTION FOR APPLICATIONS AND SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A human drug application or supplement that includes an indication for use in pediatric populations shall be assessed a fee under subparagraph (A) only if—

''(i) the application is for initial approval for use in a pediatric population; or

''(ii) the application or supplement is for approval for use in pediatric and non-pediatric populations.

''(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.'';

(2) in paragraph (2)(A), by striking ''505(j), and'' and inserting the following: ''505(j) or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or a product approved under an application under section 507 that is abbreviated, and''; and

(3) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''is listed'' and inserting ''has been submitted for listing''; and

(ii) by striking ''Such fee shall be payable'' and all that follows through ''section 510.'' and inserting the following: ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510 or for relisting if the product has been withdrawn from listing or relisted and after such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for the fiscal year in which a fee is payable.''; and

(B) in subparagraph (B), by striking ''505(j).'' and inserting the following: ''505(j) or under an abbreviated new drug application pursuant to regulations in effect prior to implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or a product approved under an application under section 507 that is abbreviated.''

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

"(1) APPLICATION FEE.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

"(2) SUPPLEMENT FEE.—The supplement fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

"(3) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

"(4) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected for

establishment fees under subsection (a)(2) in that fiscal year.''.

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking ''INCREASES AND'';

(2) in paragraph (1)—

(A) by striking ''(1) REVENUE'' and all that follows through ''increased by the Secretary'' and inserting the following: ''(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'';

(B) in subparagraph (A), by striking ''increase'' and inserting ''change'';

(C) in subparagraph (B), by striking ''increase'' and inserting ''change''; and

(D) by adding at the end the following flush sentence:

''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this provision.'';

(3) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.''

and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) so that the revenues collected from each such fee category shall be set to be equal to the revenues collected from the application and supplement fee category.''; and

(4) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(2) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) where the Secretary finds that—''

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking '', or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting '', and'';

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

"(E) the applicant is a small business submitting its first human drug application to the Secretary for review."; and

(6) by striking "In making the finding in paragraph (3)," and all that follows through "standard costs." inserting the following:

"(2) USE OF STANDARD COSTS.—In making the finding in subparagraph (C), the Secretary may use standard costs.

"(3) RULES RELATING TO SMALL BUSINESSES.—

"(A) DEFINITION.—For the purpose of paragraph (1)(E), a small business is an entity that has fewer than 500 employees, including employees of affiliates.

"(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E), the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

''(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''.

(c) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379g(f)(1)) is amended—

(1) by striking ''fiscal year 1993'' and inserting ''fiscal year 1997''; and

(2) by striking ''fiscal year 1992'' and inserting ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379g(g)) is amended—

(1) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limi-

tation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of subsection 735(6).'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''Acts'' and inserting ''Acts, or otherwise made available for obligation,''; and

(B) in subparagraph (B), by striking ''over such costs for fiscal year 1992'' and inserting ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997''; and

(3) by striking paragraph (3) and inserting the following:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

''(A) $106,800,000 for fiscal year 1998,

''(B) $109,200,000 for fiscal year 1999,

''(C) $109,200,000 for fiscal year 2000,

''(D) $114,000,000 for fiscal year 2001, and

''(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the

total amounts collected by application, supplement, establishment, and products fees.''.

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS AND FEES.—Section 736 (21 U.S.C. 379h) is amended by—

(1) redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

''(i) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person must submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due. Any requests for waivers, refunds, or exceptions must be submitted in writing to the Secretary within 1 year after the date of enactment of this subsection.''.

SEC. 705. ANNUAL REPORTS.

(a) FIRST REPORT.—Not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House

of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) SECOND REPORT.—Not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 706. EFFECTIVE DATE.

The amendments made by this title shall take effect October 1, 1997.

SEC. 707. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 4 ceases to be effective 120 days after such date.

TITLE VIII—MISCELLANEOUS

SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

''(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices that are imported or offered for the import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) The establishment shall also provide the information required by subsection (j).

''(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a) of this Act.

SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

''(4)(A) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.''

''(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (B).

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in paragraph (1), in the fifth sentence, by striking ''paragraphs (1) and (2) of section 801(e)'' and inserting ''subparagraphs (A) and (B) of section 801(e)(1)''; and

(2) by inserting after the fifth sentence the following: ''Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.''

SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 206, is further amended by adding at the end the following:

"SEC. 908. RESEARCH TRAINING AWARD PROGRAM.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support research training in regulatory scientific programs by predoctoral and postdoctoral scientists and physicians, including the use of fellowships.

"(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

"(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships through a Cooperative Research and Development Agreement.".

SEC. 805. ENFORCEMENT AUTHORITY FOR SPECIAL CONTROLS.

(a) ADULTERATED PROVISIONS.—Section 501(e) as amended by section 205, is amended by striking subparagraph (1) and inserting the following: "(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard or a special control estab-

lished under section 514, unless such device is in all respects in conformity with such standard or special control.''.

(b) MISBRANDED PROVISIONS.—Section 502(s) (21 U.S.C. 352(s)) is amended to read as follows:

''(s) If it is a device subject to a performance standard or a special control established or recognized under section 514, unless the device bears such labeling as may be prescribed in such standard or special control.''.

SEC. 806. DEVICE SAMPLES.

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

''(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit samples of such device and of components of the device as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A)) is amended by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)''.

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360(a)) is amended—

(1) in paragraph (8), by striking ''; and'' and inserting a semicolon;

(2) in paragraph (9), by striking ''made.'' and inserting ''made; and'';

(3) by inserting after paragraph (9) the following:

''(10) may reasonably require a manufacturer, importer, or distributor to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

SEC. 807. INTERSTATE COMMERCE.

(a) FINDINGS.—Congress finds that—

(1) in order to make effective the regulation of interstate commerce involving devices, foods, drugs, and cosmetics, it is necessary to impose equivalent requirements on intrastate commerce involving adulterated and misbranded devices, foods, drugs, and cosmetics as imposed on interstate commerce in such articles;

(2) without the presumption of a connection with interstate commerce, intrastate commerce involving adulterated and misbranded devices, foods, drugs, and cosmetics would discriminate against and depress interstate commerce in devices, foods, drugs, and cosmetics, and adversely burden, obstruct, and affect such interstate commerce; and

(3) transactions involving adulterated and misbranded devices, foods, drugs, and cosmetics constitute a class of activities that have a deleterious effect on the public health and welfare.

(b) DEFINITION.—Section 201(b) (21 U.S.C. 321(b)) is amended—

(1) by striking ''and (2) commerce'' and inserting ''(2) commerce'';

(2) by inserting before the period the following: '', and (3) commerce involving any article or class of

~~activities that directly or indirectly affects interstate commerce pursuant to section 709''.~~

~~(c) SEIZURE.—Section 304(a)(2)(D) (21 U.S.C. 334(a)(2)(D)) is amended to read as follows: ''(D) Any adulterated or misbranded device, food, drug, or cosmetic.''.~~

~~(d) PRESUMPTION.—Section 709 (21 U.S.C. 379a) is amended by striking ''a device'' and inserting ''a device, food, drug, or cosmetic''.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Modernization and Accountability Act of 1997''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. REFERENCES.

Except as otherwise expressly provided, wherever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

TITLE I—IMPROVING PATIENT ACCESS

SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) by inserting after subsection (a) the following:

"(b) MISSION.—

"(1) IN GENERAL.—The Administration shall protect the public health by ensuring that—

"(A) foods are safe, wholesome, sanitary, and properly labeled;

"(B) human and veterinary drugs are safe and effective;

"(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

"(D) cosmetics are safe; and

"(E) public health and safety are protected from electronic product radiation.

"(2) SPECIAL RULES.—The Administration shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Administration shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.".

SEC. 102. EXPEDITED ACCESS TO INVESTIGATIONAL THERAPIES.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SUBCHAPTER D—UNAPPROVED THERAPIES AND DIAGNOSTICS

"SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

"(a) IN GENERAL.—Any person, acting through a physician licensed in accordance with State law, may request

from a manufacturer or distributor, and any manufacturer or distributor may provide to a person after compliance with the provisions of this section, an investigational drug (including a biological product) or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition, or any other disease or condition designated by the Secretary as appropriate for expanded access under this section if—

"(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved;

"(2) the licensed physician determines that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

"(3) the Secretary determines that an exemption for the investigational drug or investigational device is in effect under a regulation promulgated pursuant to section 505(i) or 520(g) and the sponsor of the drug or device and investigators comply with such regulation;

"(4) the Secretary determines that the manufacturer of the investigational drug or investigational de-

vice is actively pursuing marketing approval with due diligence;

"(5) the Secretary determines that expanded access to the investigational drug or investigational device will not interfere with adequate enrollment of patients by the investigator in the ongoing clinical investigation of the investigational drug or investigational device authorized under section 505(i) or 520(g); and

"(6) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the expanded use of the investigational drug or investigational device in accordance with this section.

"(b) PROTOCOLS.—A manufacturer or distributor may submit to the Secretary 1 or more expanded access protocols covering expanded access use of a drug or device described in subsection (a). The protocols shall be subject to the provisions of section 505(i) or 520(g) and may include any form of use of the drug or device outside a clinical investigation, prior to approval of the drug or device for marketing, including protocols for treatment use, emergency use, or uncontrolled trials, and single patient protocols. If the request for expanded access to an investigational drug or investigational device is intended for a single patient only, the Secretary may waive the requirements of paragraphs (3) and

(4) of subsection (a) and accept a submission under section 505(i) or 520(g) for an exemption for the investigational drug or investigational device for the single patient use. In the case of an emergency that does not allow sufficient time for a submission under section 505(i) or 520(g), the Secretary may, prior to the submission, authorize the shipment of the investigational drug or investigational device for a single patient use.

"(c) NOTIFICATION OF AVAILABILITY.—The Secretary shall inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this section, except that this subsection shall not apply to expanded access protocols for single patient use.

"(d) TERMINATION.—The Secretary may at anytime terminate expanded access provided under subsection (a) for an investigational drug or investigational device if the requirements under this section are no longer met.".

SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding at the end the following flush sentences:

"The request shall be in the form of an application submitted to the Secretary. Not later than 60 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.";

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after "(2)(A)" the following: ", unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and makes a good faith effort to obtain the approval, and does not receive a timely response from an institutional review committee on the request of the physician for approval to use the device for such treatment or diagnosis"; and

(B) by adding at the end the following flush sentences:

"In a case in which a physician described in subparagraph (B) uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use."; and

(3) by striking paragraph (5) and inserting the following:

"(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.".

TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

SEC. 201. INTERAGENCY COLLABORATION.

Section 903(b) (21 U.S.C. 393(b)), as added by section 101(2), is amended by adding at the end the following:

"(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.".

SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.

It is the sense of the Committee on Labor and Human Resources of the Senate that—

(1) the Secretary of Health and Human Services should support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States;

(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.

SEC. 203. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 906. CONTRACTS FOR EXPERT REVIEW.

"(a) IN GENERAL.—

"(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Secretary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

"(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1). Such improvement may include providing the Secretary increased scientific or technical

expertise that is necessary to review or evaluate new therapies and technologies.

"(b) REVIEW OF EXPERT REVIEW.—

"(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter within 60 days after receiving the recommendations.

"(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).

"(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, the approval or disapproval of a biologics license with respect to a biological product under section 351(a) of the Public Health Service Act, or the classification of an article as a device under section 513(f)(1).".

SEC. 204. ACCREDITED-PARTY REVIEWS.

Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 523. ACCREDITED-PARTY PARTICIPATION.

"(a) ACCREDITATION.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit entities or individuals who are not employees of the Federal Government, to review reports made to the Secretary under section 510(k) for devices and make recommendations to the Secretary regarding the initial classification of such devices under section 513(f)(1), except that this paragraph shall not apply to reports made to the Secretary under section 510(k) for devices that are—

"(A) life-supporting;

"(B) life sustaining; or

"(C) intended for implantation in the human body for a period of over 1 year.

"(2) SPECIAL RULE.—The Secretary shall have the discretion to accredit entities or individuals who are not employees of the Federal Government—

"(A) to review reports made to the Secretary under section 510(k) for devices described in subparagraphs (A) through (C) of paragraph

(1), and make recommendations of initial classification of such devices; or

"(B) to review applications for premarket approval for class III devices under section 515 and make recommendations with respect to the approval or disapproval of such applications.

"(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.

"(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any entity or individual accredited under this section, after providing notice and an opportunity for an informal hearing, if such entity or individual acts in a manner that is substantially not in compliance with the requirements established by the Secretary under subsection (b), including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.

"(d) SELECTION AND COMPENSATION.—Subject to subsection (a)(2), a person who intends to make a report described in subsection (a), or to submit an application described in subsection (a), to the Secretary shall have the option to select an accredited entity or individual to review such report or application. Upon the request by a person to have a report or application reviewed by an accredited entity or individual, the Secretary shall identify for the person no less than 2 accredited entities or individuals from whom the selection may be made. Compensation for an accredited entity or individual shall be determined by agreement between the accredited entity or individual and the person who engages the services of the accredited entity or individual and shall be paid by the person who engages such services.

"(e) REVIEW BY SECRETARY.—

"(1) IN GENERAL.—The Secretary shall require an accredited entity or individual, upon making a recommendation under this section with respect to an initial classification of a device or approval or disapproval of an application for premarket approval, to notify the Secretary in writing of the reasons for such recommendation.

"(2) TIME PERIOD FOR REVIEW.—

"(A) INITIAL CLASSIFICATION.—Not later than 30 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

"(B) PREMARKET APPROVAL.—Not later than 60 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an approval or disapproval of an application for a device, the Secretary shall make a determination with respect to the approval or disapproval.

"(3) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1), or the approval or disapproval of the application under section 515(d), that is recommended by the accredited entity or individual under this section, and in such case shall notify in writing the person making the report or application described in subsection (a) of the detailed reasons for the change.

"(f) DURATION.—The authority provided by this section terminates—

"(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review devices for each of at least 70 percent of the generic types of devices subject to review under subsection (a); or

"(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices that are subject to review under subsection (a), and that were the subject of final action by the Secretary in the fiscal year preceding the date of such notification, were reviewed by the Secretary under subsection (e),

whichever occurs first.

"(g) REPORT.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited entities and individuals to conduct reviews under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).

"(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited entities and individuals to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited entities and individuals (including data on the review times, recommendations, and compensation of the entities and individuals), and data on the review of the Secretary (including data on the review times, changes, and reasons for changes of the Secretary).".

SEC. 205. DEVICE PERFORMANCE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

"Recognition of a Standard

"(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet premarket submission requirements or

other requirements under this Act to which such standards are applicable.

"(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.

"(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under this Act.

"(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

"(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

"(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

"(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

"(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.".

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(x) The falsification of a declaration of conformity submitted under subsection (c) of section 514 or the failure or refusal to provide data or information requested by the Secretary under section 514(c)(3).".

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking "(e)" and inserting "(e)(1)"; and

(2) by inserting at the end the following:

"(2) If it is, declared to be, purports to be, or is represented as, a device that is in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.".

TITLE III—IMPROVING COLLABORATION AND COMMUNICATION

SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

"(C)(i)(I) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will pro-

vide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

"(II) Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary—

"(aa) that such data are necessary to establish device effectiveness; and

"(bb) that no other less burdensome means of evaluating device effectiveness is available that would have a reasonable likelihood of resulting in an approval.

"(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless—

"(I) such determination by the Secretary would be contrary to the public health; or

"(II) based on new information (other than the information reviewed by the Secretary in making such determination) obtained by the Secretary prior to the approval of an application for an investigational device exemption under section 520(g), the Secretary finds that such determination is scientifically inappropriate.".

SEC. 302. COLLABORATIVE REVIEW PROCESS.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking "paragraph (2) of this subsection" each place it appears and inserting "paragraph (4)";

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (1) the following:

"(2)(A)(i) The Secretary shall, upon the written request of the applicant involved, meet with the applicant not later than 100 days after the receipt of an application, from the applicant, that has been filed as complete under subsection (c), to discuss the review status of the application.

"(ii) If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting, provide to the applicant a description of any deficiencies in the application identified by the Secretary and identify the information (other than information the Secretary needs to make a finding under paragraph (4)(C)) that is required to bring the application into an approvable form.

"(iii) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

"(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).".

TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES

SEC. 401. POLICY STATEMENTS.

Section 701(a) (21 U.S.C. 371(a)) is amended—

(1) by striking "(a) The" and inserting "(a)(1) The"; and

(2) by adding at the end the following:

"(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.".

SEC. 402. PRODUCT CLASSIFICATION.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"SUBCHAPTER D—CLASSIFICATION OF PRODUCTS AND ENVIRONMENTAL IMPACT REVIEWS

"SEC. 741. CLASSIFICATION OF PRODUCTS.

"(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act, may submit a request to the Secretary respecting the classification of an article (including an article that is a combination product subject to section 503(g)) as a drug, biological product, or device, or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or a component to regulate the article, as appropriate.

"(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.

"(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.".

SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.

(a) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

"(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

"(i) approving another device;

"(ii) determining whether a product development protocol has been completed, under section 515 for another device;

"(iii) establishing a performance standard or special control under this Act; or

"(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

"(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency action described in subparagraph (A).".

(b) CONFORMING AMENDMENT.—Section 517(a) (21 U.S.C. 360g(a)) is amended—

(1) in paragraph (8), by adding "or" at the end;

(2) in paragraph (9), by striking ", or" and inserting a comma; and

(3) by striking paragraph (10).

SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.

(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:

"In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither

false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.".

(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

"(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.

"(D) The determinations of the Secretary under this section and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in proposed labeling of the device submitted in a report under section 510(k).".

SEC. 405. DEFINITION OF A DAY FOR PURPOSES OF PRODUCT REVIEW.

Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(ii) In any provision relating to a review of any application or submission (including a petition, notification, and any other similar form of request), made under this Act with respect to an article that is a new drug, device, biological product, new animal drug, an animal feed bearing or containing a new animal drug, color additive, or food additive, that is submitted to the Secretary to obtain marketing approval, to obtain classification of a device under section 513(f)(1), or to establish or clarify the regulatory status of the article—

"(1) the term 'day' means a calendar day in which the Secretary has responsibility to review such an application or submission; and

"(2) a reference to a date relating to the receipt of such an application or submission by the Secretary shall be deemed to be a reference to the date on which the Secretary receives a complete application or submission within the meaning of this Act and the regulations promulgated under this Act.".

SEC. 406. CERTAINTY OF REVIEW TIMEFRAMES.

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

"The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the notification.".

(b) CERTAINTY OF 180-DAY REVIEW TIMEFRAME.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

"(3) Except as provided in paragraph (1), the period for the review of an application by the Secretary under this subsection shall be not more than 180 days. Such period may not be restarted or extended even if the application is amended.".

SEC. 407. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

"(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f).".

SEC. 408. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.

Not later than 270 days after the date of enactment of this section, the Secretary of Health and Human Services shall promulgate a final regulation specifying the general principles that the Secretary of Health and Human Services will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

SEC. 409. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking "clinical investigations" and inserting "1 or more clinical investigations".

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: "Substantial evidence may, as appropriate, consist of data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation), if the Secretary determines, based on relevant science, that such data and evidence are sufficient to establish effectiveness.".

SEC. 410. PROHIBITED ACTS.

Section 301(l) (21 U.S.C. 331(l)) is repealed.

TITLE V—IMPROVING ACCOUNTABILITY

SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

"(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

"(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall estab-

lish objectives, and mechanisms to be used by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

"(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

"(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

"(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

"(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

"(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods specified in this Act for the review of all applica-

tions and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

"(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

"(5) ANNUAL REPORT.—

"(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

"(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

"(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

"(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

"(iv) identifies any regulatory policy that has a significant impact on compliance

with any objective of the plan or any statutory obligation; and

"(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

"(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

"(i) the submission of any investigational application;

"(ii) the application of any clinical hold;

"(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

"(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

"(v) the occurrence of any unapprovable action;

"(vi) the occurrence of any approvable action; and

"(vii) the approval or clearance of any application or submission described in clause (iii).".

TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

SEC. 601. MINOR MODIFICATIONS.

(a) ACTION ON INVESTIGATIONAL DEVICE EXEMPTIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

"(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from the requirements of this Act.

"(B) The regulation shall permit developmental changes in a device (including manufacturing changes) in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to such application, if the sponsor of the investigation determines, based on credible information, prior to making any such changes, that the changes—

"(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

"(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.".

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

"(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g), to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

"(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

"(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.".

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

"(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and

informs the Secretary that the change has been made under the requirements of section 520(f).

"(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device shall not distribute the device for a period of 14 days after the date on which the Secretary receives the notice.

"(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

"(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

"(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

"(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification to provide a reasonable assurance of safety and effectiveness.".

SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

"SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

"Notwithstanding any other provision of law, no action by the Secretary pursuant to this Act shall be subject to an environmental assessment, an environmental impact statement, or other environmental consideration unless the Secretary demonstrates, in writing—

"(1) that there is a reasonable probability that the environmental impact of the action is sufficiently substantial and within the factors that the Secretary is authorized to consider under this Act; and

"(2) that consideration of the environmental impact will directly affect the decision on the action.".

SEC. 603. EXEMPTION OF CERTAIN CLASSES OF DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.

(a) CLASS I AND CLASS II DEVICES.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking "intended for human use" and inserting "intended for human use (except a device that is classified into class I under section 513 or 520 unless the Secretary determines such device is intended for a use that is of substantial importance in preventing impairment of human health or such device pre-

sents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))".

(b) PUBLICATION OF EXEMPTION.—Section 510 (21 U.S.C. 360) is amended by inserting after subsection (k) the following:

"(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k) as of the date of the publication of the list in the Federal Register.

"(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the notification requirement of subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such notification is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and pro-

vide a 30-day comment period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.".

SEC. 604. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking "paragraph (2)" and inserting "paragraph (3)"; and

(B) in the last sentence, by striking "paragraph (2)" and inserting "paragraph (2) or (3)";

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

"(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Sec-

retary to classify the device into class I or II under the criteria set forth in subparagraphs (A) through (C) subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. The request shall describe the device and provide detailed information and reasons for the recommended classification.

"(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), the Secretary shall by written order classify the device. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph into class I or II shall be a predicate device for determining substantial equivalence under paragraph (1).

"(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

"(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.".

SEC. 605. SECRETARY'S DISCRETION TO TRACK DEVICES.

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

"Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.".

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)). Each device not identified by the Secretary of Health and Human Services under this subsection or designated by the Secretary under section 519(e)(2) shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act. The Secretary of Health and Human Services shall have authority to modify the list of devices exempted from the mandatory tracking requirements.

SEC. 606. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.

(a) IN GENERAL.—Section 522 (21 U.S.C. 360l) is amended by striking "SEC. 522." and all that follows through "(2) DISCRETIONARY SURVEILLANCE.—The" and inserting the following:

"SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The".

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360l(b)) is amended to read as follows:

"(b) SURVEILLANCE APPROVAL.—

"(1) IN GENERAL.—Each manufacturer that receives notice from the Secretary that the manufacturer is required to conduct surveillance of a device under subsection (a) shall, not later than 30 days after receiving the notice, submit for the approval of the Secretary, a plan for the required surveillance.

"(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed in the plan to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

"(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.".

(c) DURATION OF SURVEILLANCE.—Section 522 (21 U.S.C. 360l), as amended by subsection (b), is further amended by adding at the end the following:

"(c) DURATION OF SURVEILLANCE.—

"(1) IN GENERAL.—Each manufacturer required to conduct surveillance of a device under subsection (a) shall be required to conduct such surveillance for not longer than 24 months.

"(2) EXTENSION OF THE PERIOD OF SURVEILLANCE.—If the Secretary determines that additional surveillance is needed to identify the incidence of adverse events documented during the initial period of surveillance that were not foreseen at the time of approval or classification of the device, the Secretary may extend the period of surveillance for such time as may be necessary after providing the person required to conduct such surveillance an opportunity for an informal hearing to determine whether or not additional surveillance is appropriate and to determine the appropriate period, if any, for such surveillance.".

SEC. 607. REPORTING.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the first sentence by striking ''make such reports, and provide such information,'' and inserting ''and submit such samples and components of devices (as required by paragraph (10)),''; and

(B) by inserting after the first sentence the following: ''Every person who is a manufacturer or importer of a device intended for human use shall make reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to assure the safety and effectiveness of such device.'';

(C) in the last sentence by striking ''sentence'' and inserting ''sentences'';

(D) in paragraph (8), by striking ''; and'' and inserting a semicolon; and

(E) by striking paragraph (9) and inserting the following:

''(9) shall require distributors to keep records and make such records available to the Secretary upon request; and'';

(2) by striking subsection (d); and

(3) in subsection (f), by striking ", importer, or distributor" each place it appears and inserting "or importer".

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3), the following:

"(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or"; and

(3) by adding at the end the following flush sentence:

"In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.".

SEC. 608. PILOT AND SMALL-SCALE MANUFACTURE.

Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

"(4) A new drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the

new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.''.

SEC. 609. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include (but not be limited to) consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological

activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, 1 or more disease states.

(b) DEFINITION.—In this section, the term "radiopharmaceutical" means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 610. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

"(a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

"(A) a biologics license is in effect for the biological product; and

"(B) each package of the biological product is plainly marked with—

"(i) the proper name of the biological product contained in the package;

"(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

"(iii) the expiration date of the biological product.

"(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

"(B) The Secretary shall approve a biologics license application on the basis of a demonstration that—

"(i) the biological product that is the subject of the application is safe, pure, and potent; and

"(ii) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

"(3) A biologics license application shall be approved only if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).".

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking "(d)(1)" and all that follows through "of this section.";

(B) in paragraph (2)—

(i) by striking "(2)(A) Upon" and inserting "(d)(1) Upon;" and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking "subparagraph (A)" and inserting "paragraph (1)"; and

(ii) by striking "this subparagraph" each place it appears and inserting "this paragraph".

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

"(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.".

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking "virus, serum," and all that follows and inserting "biological product.".

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.".

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking "section 351(a)" and inserting "section 351(i)"; and

(B) by striking "262(a)" and inserting "262(i)"; and

(2) in subparagraph (B)(iii), by striking "product or establishment license under subsection (a) or (d)" and inserting "biologics license application under subsection (a)".

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under sec-

tion 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

SEC. 611. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing

the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary of Health and Human Services shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary of Health and Human Services shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 612. HEALTH CARE ECONOMIC INFORMATION.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

"(u) In the case of a health care economic statement that is included in labeling or advertising provided to a formulary committee, managed care organization, or similar entity with responsibility for drug selection decisions (other than the label or approved physician package insert) relating to an indication approved under section 505 or 351 of the Public Health Service Act (42 U.S.C. 262), if the health care economic statement is not based on competent and reliable scientific evidence. The only requirements applicable to any such statement under this Act shall be the requirements of this paragraph. In this paragraph, the term 'health care economic statement' means any statement that identifies, measures, or compares the costs (direct, indirect, and intangible) and health care consequences of a drug to another drug, to another health care intervention for the same indication, or to no intervention, where the primary endpoint is an economic outcome.".

SEC. 613. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

"SUBCHAPTER E—FAST TRACK DRUGS

"SEC. 561. FAST TRACK DRUGS.

"(a) DESIGNATION OF DRUG AS A FAST TRACK DRUG.—

"(1) IN GENERAL.—The Secretary shall facilitate development, and expedite review and approval of new drugs and biological products that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this Act, such products shall be known as 'fast track drugs'.

"(2) REQUEST FOR DESIGNATION.—The sponsor of a drug (including a biological product) may request the Secretary to designate the drug as a fast track drug. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(4) of the Public Health Service Act.

"(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the

drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.

"(b) APPROVAL OF APPLICATION FOR A FAST TRACK DRUG.—

"(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track drug under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.

"(2) LIMITATION.—Approval of a fast track drug under this subsection may be subject to the requirements—

"(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug; and

"(B) that the sponsor submit copies of all promotional materials related to the fast track drug during the preapproval review period and following approval, at least 30 days prior to dissemination of the materials for such period of time as the Secretary deems appropriate.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track drug using expedited procedures (as prescribed by the Secretary in regulations) including a procedure that provides an opportunity for an informal hearing, if—

"(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

"(B) a post-approval study of the fast track drug fails to verify clinical benefit of the fast track drug;

"(C) other evidence demonstrates that the fast track drug is not safe or effective under conditions of use of the drug; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the fast track drug.

"(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK DRUG.—

"(1) IN GENERAL.—If preliminary evaluation by the Secretary of clinical efficacy data for a fast track drug under investigation shows evidence of effectiveness, the Secretary shall evaluate for filing, and may commence review of portions, of an application for the approval of the drug if the applicant provides a

schedule for submission of information necessary to make the application complete and any fee that may be required under section 736.

"(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) AWARENESS EFFORTS.—The Secretary shall—

"(1) develop and widely disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a comprehensive description of the provisions applicable to fast track drugs established under this section; and

"(2) establish an ongoing program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.".

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track drugs that describes the policies and procedures that pertain to section 561 of the Federal Food, Drug, and Cosmetic Act.

SEC. 614. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.

(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:

"SUBCHAPTER E—MANUFACTURING CHANGES

"SEC. 751. MANUFACTURING CHANGES.

"(a) IN GENERAL.—A change in the manufacture of a new drug, including a biological product, may be made in accordance with this section.

"(b) CHANGES.—

"(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, or license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency of the drug as the identity,

strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

"(2) REPORTS.—The applicant shall report the change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:

"(A) MAJOR MANUFACTURING CHANGES.

"(i) IN GENERAL.—Major manufacturing changes, which are of a type determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.

"(ii) DEFINITION.—In this subparagraph, the term 'major manufacturing changes' means—

"(I) changes in the qualitative or quantitative formulation of a drug or the specifications in the approved mar-

keting application for the drug (unless exempted by the Secretary from the requirements of this subparagraph);

"(II) changes that the Secretary determines by regulation or issuance of guidance require completion of an appropriate human study demonstrating equivalence of the drug to the drug manufactured before such changes; and

"(III) other changes that the Secretary determines by regulation or issuance of guidance have a substantial potential to adversely affect the safety or effectiveness of the drug.

"(B) OTHER MANUFACTURING CHANGES.—

"(i) IN GENERAL.—As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—

"(I) be made at any time and reported annually to the Secretary, with supporting data; or

"(II) be reported to the Secretary in a supplemental application.

"(ii) DISTRIBUTION OF THE DRUG.—In the case of changes reported in accordance with clause (i)(II)—

"(I) the applicant may distribute the drug 30 days after the Secretary receives the supplemental application unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required; and

"(II) the Secretary shall, after making the notification to the applicant under subclause (I), approve or disapprove each such supplemental application.

"(iii) SPECIAL RULE.—The Secretary may determine types of manufacturing changes after which distribution of a drug may commence at the time of submission of such supplemental application.".

(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) that are in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect—

(1) for a period of 24 months after the date of enactment of this Act; or

(2) until the effective date of regulations promulgated by the Secretary of Health and Human Services implementing section 751 of the Federal Food, Drug, and Cosmetic Act,

whichever is sooner.

SEC. 615. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 616. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subsection (j)"; and

(B) by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

"(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

"(B) a notification submitted under subsection (h) that is effective."; and

(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive

in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).".

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

"Notification Relating to a Food Contact Substance

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information required to be submitted by regulations promulgated by the Secretary.

"(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by

the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

"(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

"(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

"(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

"(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be based on the resources required to process the notification including reasonable administrative costs for such processing.

"(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of the Food and Drug Administration Modernization and Ac-

countability Act of 1997, promulgate regulations establishing the fee required by subparagraph (A).

"(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of subsection (a)(3) until the appropriate fee is paid.

"(D) Fees collected pursuant to this subsection—

"(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

"(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

"(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

"(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.";

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: "The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective."; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking "subsections (b) to (h)" and inserting "subsections (b) to (i)".

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

SEC. 617. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

"(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) that is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made if—

"(i) an authoritative scientific body of the Federal Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or a subdivision of the scientific body or the National Academy of Sciences, has published an authoritative statement, which is currently in effect, about the relationship be-

tween a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary at least 90 days before the first introduction of a food into interstate commerce a notice of the claim, including a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied;

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii), and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this paragraph, a statement shall be regarded as an authoritative statement of such a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(D) A claim meeting the requirements of clause (C) may be made until—

"(i) such time as the Secretary issues a final regulation under clause (B) prohibiting or modifying the claim, and the regulation has become effective; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.".

SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1) the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the re-

ports thereof are accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under section

505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV), and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharma-

copoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

"(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II) and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV), and in the patent infringement litigation resulting from the certification the court de-

termines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

"(A) the sponsor of an application for an investigational new drug under section 505(i);

"(B) the sponsor of an application for a drug under section 505(b)(1); or

"(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

"(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement re-

ferred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

"(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

"(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j), respectively, until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

"(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under section 505(b)(2) or (j) for a drug will be subject to the provisions of this section.

"(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least 1 clinical investigation (that, at the Secretary's discretion, may include

pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.

"(h) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

"(i) SUNSET.—No period of market exclusivity shall be granted under this section based on studies commenced after January 1, 2004. The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

"(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

"(2) the adequacy of the incentive provided under this section;

"(3) the economic impact of the program; and

"(4) any suggestions for modification that the Secretary deems appropriate.".

SEC. 619. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 405, is further amended by adding at the end the following:

"(jj) The term 'compounded positron emission tomography drug' means a drug that—

"(1) exhibits spontaneous disintegration of unstable nuclei, including the emission of positrons;

"(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of any such drug; and

"(3)(A) has been compounded in a State in accordance with State law for a patient or for research, teaching, or quality control by or on the order of a practitioner licensed by that State to compound or order such a drug; or

"(B) has been compounded in a Federal facility in a State in accordance with the law of the State in which the facility is located.".

(b) REGULATION AS A DRUG.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking "; or (3)" and

inserting the following: "; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3)".

(c) REGULATION AS A NEW DRUG.—Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

"(n) The provisions of subsections (a) and (j) shall not apply to the preparation of a compounded positron emission tomography drug.".

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice revoking—

(1) a notice entitled "Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop", published in the Federal Register of February 27, 1995;

(2) a notice entitled "Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products", published in the Federal Register of April 22, 1997; and

(3) a final rule entitled "Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography", published in the Federal Register of April 22, 1997.

TITLE VII—FEES RELATING TO DRUGS

SEC. 701. SHORT TITLE.

This title may be cited as the "Prescription Drug User Fee Reauthorization Act of 1997".

SEC. 702. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of _____, and _____, from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth at ____ Cong. Rec. _____ (daily ed. _____, 1997).

SEC. 703. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking "Service Act, and" and inserting "Service Act,"; and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug or biological product that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.";

(2) in the second sentence of paragraph (3)—

(A) by striking "Service Act, and" and inserting "Service Act,"; and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug or biological product that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does

include a large volume biological product intended for single dose injection for intravenous use or infusion.";

(3) in paragraph (4), by striking "without" and inserting "without substantial";

(4) in paragraph (7)(A)—

(A) by striking "employees under contract" and all that follows through "Administration," and inserting "contractors of the Food and Drug Administration,"; and

(B) by striking "and committees," and inserting "and committees and to contracts with such contractors,";

(5) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking "August of" and inserting "April of"; and

(ii) by striking "August 1992" and inserting "April 1997";

(B) by striking subparagraph (B) and inserting the following:

"(B) 1 plus the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code,

as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia."; and

(C) by striking the second sentence; and

(6) by adding at the end the following:

"(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) 1 business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has power to control both of the business entities.".

SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) by striking "Beginning in fiscal year 1993" and inserting "Beginning in fiscal year 1998";

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

"(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.";

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking "NOT ACCEPTED" and inserting "REFUSED";

(ii) by striking "50 percent" and inserting "75 percent";

(iii) by striking "subparagraph (B)(i)" and inserting "subparagraph (B)"; and

(iv) by striking "not accepted" and inserting "refused"; and

(C) by adding at the end the following:

"(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A person that submits a human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526, or a supplement proposing to include a new indication for a rare disease or condition pursuant to section 526, shall not be assessed a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions.

"(F) EXCEPTION FOR APPLICATIONS AND SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A person that submits a human drug application or supplement that includes an indication for

use in pediatric populations shall be assessed a fee under subparagraph (A) only if—

"(i) the application is for initial approval for use in a pediatric population; or

"(ii) the application or supplement is for approval for use in pediatric and non-pediatric populations.

"(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.";

(3) in paragraph (2)(A), by striking "505(j), and" and inserting the following: "505(j) or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restora-

tion Act of 1984, or a product approved under an application filed under section 507 that is abbreviated, and"; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking "is listed" and inserting "has been submitted for listing"; and

(ii) by striking "Such fee shall be payable" and all that follows through "section 510." and inserting the following: "Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(B) in subparagraph (B), by striking "505(j)." and inserting the following: "505(j), or under an abbreviated new drug application pursuant to regulations in effect prior to the imple-

mentation of the Drug Price Competition and Patent Term Restoration Act of 1984, or is a product approved under an application filed under section 507 that is abbreviated.".

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

"(1) APPLICATION AND SUPPLEMENT FEES.—

"(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

"(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

"(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each

of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

"(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.".

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking "INCREASES AND";

(2) in paragraph (1)—

(A) by striking "(1) REVENUE" and all that follows through "increased by the Secretary" and inserting the following: "(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary";

(B) in subparagraph (A), by striking "increase" and inserting "change";

(C) in subparagraph (B), by striking "increase" and inserting "change"; and

(D) by adding at the end the following flush sentence:

"The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.";

(3) in paragraph (2), by striking "October 1, 1992," and all that follows through "such schedule." and inserting the following: "September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected during the past fiscal year from the category of application and supplement fees described in paragraph (1) of subsection (b)."; and

(4) in paragraph (3), by striking "paragraph (2)" and inserting "this subsection".

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(2) by striking "The Secretary shall grant a" and all that follows through "finds that—" and inserting the following:

"(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—";

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking ", or" and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting ", or";

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

"(E) the applicant is a small business submitting its first human drug application to the Secretary for review."; and

(6) by striking "In making the finding in paragraph (3)," and all that follows through "standard costs." and inserting the following:

"(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

"(3) RULES RELATING TO SMALL BUSINESSES.—

"(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that

has fewer than 500 employees, including employees of affiliates.

"(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

"(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

"(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.".

(e) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking "fiscal year 1993" and inserting "fiscal year 1997"; and

(2) by striking "fiscal year 1992" and inserting "fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)".

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: "Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).";

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "Acts" and inserting "Acts, or otherwise made available for obligation,"; and

(B) in subparagraph (B), by striking "over such costs for fiscal year 1992" and inserting "over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997"; and

(3) by striking paragraph (3) and inserting the following:

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

"(A) $106,800,000 for fiscal year 1998;

"(B) $109,200,000 for fiscal year 1999;

"(C) $109,200,000 for fiscal year 2000;

"(D) $114,000,000 for fiscal year 2001; and

"(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

"(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year, shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.".

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

"(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund, of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.".

(h) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees paid prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

SEC. 705. ANNUAL REPORTS.

(a) FIRST REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Com-

mittee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) SECOND REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 706. EFFECTIVE DATE.

The amendments made by this title shall take effect October 1, 1997.

SEC. 707. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 705 ceases to be effective 120 days after such date.

TITLE VIII—MISCELLANEOUS

SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

"(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

"(2) The establishment shall also provide the information required by subsection (j).

"(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).".

SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

"(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

"(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).".

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking "section 502(d) and".

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking "(i)"; and

(B) by striking "(ii)" and all that follows.

SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in paragraph (1), in the fifth sentence, by striking "paragraphs (1) and (2) of section 801(e)" and inserting "subparagraphs (A) and (B) of section 801(e)(1)"; and

(2) by inserting after the fifth sentence the following: "Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.".

SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 203, is further amended by adding at the end the following:

"SEC. 907. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support intramural research training in regulatory scientific programs by predoctoral and postdoctoral scientists

and physicians, including the support through the use of fellowships.

"(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

"(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships described in subsection (a) through a Cooperative Research and Development Agreement.".

SEC. 805. DEVICE SAMPLES.

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

"(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit such samples of the device and of components of the device as the Secretary may reasonably require. If the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.".

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A) (21 U.S.C. 360h(e)(2)(A)) is amended by striking "subparagraphs (B) and (C)" and inserting "subparagraph (B)".

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360i(a)) is amended by inserting after paragraph (9) the following:

"(10) may reasonably require a manufacturer, importer, or distributor to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that if the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.".

SEC. 806. INTERSTATE COMMERCE.

Section 709 (21 U.S.C. 379a) is amended by striking "a device" and inserting "a device, food, drug, or cosmetic".

SEC. 807. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 614, is further amended by adding at the end the following:

"SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS FOR HUMAN USE AND COSMETICS

"SEC. 761. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

"(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), or (d), no State or political subdivision of a State may establish or continue in effect any requirement—

"(1) that relates to the regulation of a drug intended for human use that is not subject to the requirements of section 503(b)(1) or a cosmetic; and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement of this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such condition as may be prescribed in such regulation, a State requirement that—

"(1) protects an important public interest that would otherwise be unprotected;

"(2) would not cause any drug or cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

"(3) would not unduly burden interstate commerce.

"(c) SCOPE.—For purposes of subsection (a), a requirement that relates to the regulation of a drug or cosmetic—

"(1) shall not include any requirement that relates to the practice of pharmacy or any requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug; and

"(2) shall be deemed to include any requirement relating to public information or any other form of public communication relating to the safety or effectiveness of a drug or cosmetic.

"(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.".

SEC. 808. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following:

"(j)(1) The Secretary, acting through the Director of the National Institutes of Health and subject to the availability of appropriations, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

"(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of informa-

tion on clinical trials for drugs, and biologicals, for serious or life-threatening diseases and conditions.

"(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

"(3) The Data Bank shall include the following:

"(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 and 520 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug or biological protocol, either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the Data Bank by

the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

"(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

"(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations; or

"(ii) as a Group C cancer drug.

The Data Bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

"(4) The Data Bank shall not include information relating to an investigation if the sponsor has certified to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation.

"(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic (21 U.S.C. 379h) shall not be

authorized or appropriated for use in carrying out this subsection.".

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report that shall consider, among other things—

(A) the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act; and

(B) the adverse impact, if any, on device innovation and research in the United States if

information relating to such device investigations is required to be publicly disclosed.

SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

"(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

"(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

"(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

"(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an estab-

lished relationship between the licensed pharmacist, or licensed physician, and—

"(I) the individual patient for whom the prescription order will be provided; or

"(II) the physician or other licensed practitioner who will write such prescription order; and

"(B) the licensed pharmacist or licensed physician—

"(i) compounds the drug product using bulk drug substances—

"(I) that—

"(aa) comply with the standards of an applicable United States Pharmacopeia monograph; or

"(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

"(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

"(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia monograph and the United States Pharmacopeia chapter on pharmacy compounding;

"(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

"(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

"(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an

adverse effect on the safety or effectiveness of that drug product; and

"(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary (based on the adequate regulation of compounding performed in the State) that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

"(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

"(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

"(i) the date that is 180 days after the development of the standard memorandum of understanding; or

"(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

"(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

"(4) The provisions of paragraph (1) shall not apply—

"(A) to compounded positron emission tomography drugs as defined in section 202(jj); or

"(B) to radiopharmaceuticals.".